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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,933	03/27/2007	**Galit Levin**	2488.032	2953

23405 7590 06/03/2008

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EXAMINER	
DOUKAS, MARIA E	
ART UNIT	**PAPER NUMBER**
4166	
MAIL DATE	**DELIVERY MODE**
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,933	LEVIN ET AL.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. The declaration filed 27 March 2007 indicates on page 1 that it relates to "The specification of which is attached hereto", rather than identifying the application by international application number and international filing date. See MPEP § 602.

On page 2, declaration claims benefit under claims the benefit under 35 U. S. C. Section 120 and Section 365(c) of the PCT International application designating the United States, however the application was accepted as a National stage of PCT/IL04/00561 under 35 U.S.C 371 and 37 CFR 1.495 and was granted the appropriate PCT/DO/EO/903 form.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter in claim 2 describing the apparatus comprising an electrode cartridge comprising a plurality of electrodes and a main unit comprising a control unit must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 24 is objected to because of the following informalities: the word “wrinckles” appears to be a misspelling of the word "wrinkles." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5-7, 9, 10, 12-17, 19, 20, and 22-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US Patent No. 6,302,874 to Zhang (Zhang).

Zhang teaches:

In Reference to Claim 1

A system (Figure 5A, 5B) for intradermal or transdermal delivery (col. 6, lines 61-64 define 'topical delivery' as used in col. 7, lines 6-13) of a water-soluble, poorly water-soluble, or water-insoluble cosmetic agent (col. 7, lines 45-48) comprising:

an apparatus (Figure 5A, 5B) for facilitating intradermal or transdermal delivery (col. 7, lines 6-13) of a cosmetic agent (col. 7, lines 45-48) through the skin of a subject, said apparatus capable of generating at least one micro-channel in a region on the skin of the subject (col. 2, lines 65-66 defines electroporation as used in col. 10, lines 30-40 and col. 12, lines 26-29), and a cosmetic or dermatological composition (col. 7, lines 45-48) comprising at least one water-soluble, poorly water- soluble, or water-insoluble cosmetic agent (col. 5, lines 31-35) and a cosmetically or dermatologically acceptable carrier (col. 6, lines 47-53).

In Reference to Claim 2

The system (Figure 5A, 5B) according to claim 1 (see rejection of claim 1 above), wherein the apparatus (Figure 5A, 5B) for facilitating intradermal or transdermal delivery of a cosmetic agent through skin of a subject comprises:

a. an electrode cartridge (electrode 2 of Figure 5A-B) comprising a plurality of electrodes (col. 12, lines 30-31, lines 52-53); and

b. a main unit (handheld pulser 4) comprising a control unit (col. 12, lines 26-37, col. 13, lines 5-10; switch button 8 in Figure 5B) which is adapted to apply electrical energy between two or more electrodes when the electrodes are in vicinity of the skin (col. 10, lines 30-35; col. 11, lines 18-21; col. 12, lines 26-37), generating current flow or one or more sparks, enabling ablation of stratum corneum in an area beneath the electrodes, thereby generating at least one micro-channel (col. 10, lines 30-40; col. 11, lines 18-21).

In Reference to Claim 3

The system according to claim 2 (see rejection of claim 2 above) wherein the electrode cartridge is removable (col. 14, lines 27-29).

In Reference to Claim 5

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids, α-hydroxy acids, β-hydroxy acids, α-2 adrenergic inhibitors, β-adrenergic agonists, aromatase

inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol, mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 7, lines 45-48).

In Reference to Claim 6

The system according to claim 5 (see rejection of claim 5 above), wherein the xanthine is caffeine (col. 7, lines 45-48: claim 5 lists a Markoush grouping, claim 6 further specifies xanthine from the group as caffeine, however ascorbic acid can still be chosen as the cosmetic agent from the claim 5 group, thus meeting claim 6).

In Reference to Claim 7

The system according to claim 5 (see rejection of claim 5 above), wherein the β-hydroxy acid is salicylic acid (col. 7, lines 45-48: claim 5 lists a Markoush grouping, claim 7 further specifies β-hydroxy acid from the group as salicylic acid, however ascorbic acid can still be chosen as the cosmetic agent from the claim 5 group, thus meeting claim 7).

In Reference to Claim 9

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic or dermatological composition (col. 7, lines 45-48) further comprising at least one component selected from the group consisting of surfactants, humectants, preservatives, antioxidants, powders, clarifying agents, coloring agents, opacifiers, thickeners, and perfumes (col. 8, lines 51-57).

In Reference to Claim 10

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic or dermatological composition further comprising a pharmaceutical agent (col. 6, lines 42-47 and col. 8, lines 51-54).

In Reference to Claim 12

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic or dermatological composition is formulated in a form selected from the group consisting of anhydrous compositions, aqueous solutions, aqueous suspensions, oil-in-water emulsions, water- in-oil emulsions, oily droplets in aqueous solutions, micelles, liposomes, ethosomes, and aqueous suspensions of nanoparticles (col. 6, lines 53-57).

In Reference to Claim 13

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic or dermatological composition is in a form selected from the group consisting of lotions, creams, ointments, gels, pastes, sprays, foams, sticks, and skin patches (col. 6, lines 53-57).

In Reference to Claim 14

A method for treating a skin condition in a subject (col. 5, lines 29-31) comprising the steps of:

(i) generating at least one micro-channel in a region of skin of a subject suffering from a skin condition (col. 12, lines 26-29 describe the electroporation due to the applied electric pulses, while col. 20, lines 16-18 describes the method of applying the electric pulse to the skin surface); and (ii) topically applying (col. 11, lines 28-32; col. 20, lines 18-20) a dermatologically effective amount (col. 7, lines 45-52) of a cosmetic or dermatological composition (col. 7, lines 45-48) comprising at least one water-soluble, poorly water-soluble, or water-insoluble cosmetic agent (col. 5, lines 31-35) and a cosmetically or dermatologically acceptable carrier (col. 6, lines 47-53) to the region of the skin in which at least one micro-channel is present (col. 11, lines 28-32) so as to improve the skin condition of said subject (col. 1, lines 13-17).

In Reference to Claim 15

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids, α-hydroxy acids, β-hydroxy acids, α-2 adrenergic inhibitors, β-adrenergic agonists, aromatase inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol, mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 7, lines 45-48).

In Reference to Claim 16

The method of claim 15 (see rejection of claim 15 above), wherein the xanthine is caffeine (col. 7, lines 45-48: claim 15 lists a Markoush grouping, claim 16 further specifies xanthine from the group as caffeine, however ascorbic acid can still be chosen as the cosmetic agent from the claim 5 group, thus meeting claim 16).

In Reference to Claim 17

The method according to claim 15 (see rejection of claim 15 above), wherein the β-hydroxy acid is salicylic acid (col. 7, lines 45-48: claim 15 lists a Markoush grouping, claim 17 further specifies β-hydroxy acid from the group as salicylic acid, however ascorbic acid can still be chosen as the cosmetic agent from the claim 15 group, thus meeting claim 17).

In Reference to Claim 19

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic or dermatological composition further comprising at least one component selected from the group consisting of surfactants, humectants, preservatives, antioxidants, powders, clarifying agents, coloring agents, opacifiers, thickeners, and perfumes (col. 8, lines 51-57).

In Reference to Claim 20

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic or dermatological composition further comprising a pharmaceutical agent (col. 6, lines 42-47 and col. 8, lines 51-54).

In Reference to Claim 22

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic or dermatological composition is formulated in a form selected from the group consisting of anhydrous compositions, aqueous solutions, aqueous suspensions, oil-in-water emulsions, water- in-oil emulsions, oily droplets in aqueous solutions, micelles, liposomes, ethosomes, and aqueous suspensions of nanoparticles (col. 6, lines 53-57).

In Reference to Claim 23

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic or dermatological composition is in a form selected from the group consisting of lotions, creams, ointments, gels, pastes, sprays, foams, sticks, and skin patches (col. 6, lines 53-57).

In Reference to Claim 24

The method according to claim 14 (see rejection of claim 14 above), wherein the skin condition is selected from cellulite, acne vulgaris, acne cystic, skin aging, skin wrinckles, hyperpigmentation, keratosis, skin blemish, dandruff, warts, photodamaged skin,

chronic dermatoses, dermatitis, dryness, ichthyosis, viral infections, fungal infections, and bacterial skin infections (col. 5, lines 46-67).

6. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication No. US 2002/0038101 to Avrahami (Avrahami).

In Reference to Claim 1

A system (Figure 1A) for intradermal or transdermal delivery (page 9, paragraph 0167) of a water-soluble, poorly water-soluble, or water-insoluble cosmetic agent (page 16, paragraph 0250, 0251) comprising:

an apparatus (skin puncturing device 20) for facilitating intradermal or transdermal delivery (page 9, paragraph 0167) of a cosmetic agent (page 16, paragraph 0250, 0251) through the skin of a subject, said apparatus capable of generating at least one micro-channel (page 2, paragraph 0018 defines microchannel) in a region on the skin of the subject (page 9, paragraph 0167), and a cosmetic or dermatological composition (page 15, paragraph 0232) comprising at least one water-soluble, poorly water- soluble, or water-insoluble cosmetic agent (page 16, paragraphs 0250, 0251 list beta blockers and estrogen) and a cosmetically or dermatologically acceptable carrier (page 15, paragraphs 0225, 0231-0232 name the possible use of an inert gel and describe the delivery of the active substance so as to keep it physiologically and pharmacologically active).

In Reference to Claim 2

The system (Figure 1A) according to claim 1 (see rejection of claim 1 above), wherein the apparatus (skin puncturing device 20) for facilitating intradermal or transdermal delivery of a cosmetic agent through skin of a subject comprises:

a. an electrode cartridge (skin patch 40) comprising a plurality of electrodes (electrodes 60; page 9, paragraph 0170); and

b. a main unit comprising a control unit (control unit 30) which is adapted to apply electrical energy between two or more electrodes when the electrodes are in vicinity of the skin (page 9, paragraph 0167-0170), generating current flow or one or more sparks, enabling ablation of stratum corneum in an area beneath the electrodes, thereby generating at least one micro-channel (page 9, paragraph 0170).

In Reference to Claim 4

The system according to claim 2 (see rejection of claim 2 above), wherein the electrical energy is of radio frequency (page 12, paragraph 0193 describes a driving frequency between 100 Hz and 10 MHz, which falls within the radio frequency range defined by webopedia.com to be “any frequency within the electromagnetic spectrum associated with radio wave propagation”).

7. Claims 1, 5, 8, 10, 11, 14, 15, 18, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,477,410 to Henley (Henley).

In Reference to Claim 1

A system (Figure 1) for intradermal or transdermal delivery (col. 1, lines 13-25, lines 54-57; col. 18, lines 10-11) of a water-soluble, poorly water-soluble, or water-insoluble cosmetic agent (col. 2, lines 2-6, line 40; col. 40, line 59) comprising:

an apparatus (Figure 1) for facilitating intradermal or transdermal delivery (col. 1, lines 13-25, lines 54-57; col. 18, lines 10-11) of a cosmetic agent (col. 2, lines 2-6, line 40) through the skin of a subject, said apparatus capable of generating at least one micro-channel in a region on the skin of the subject (col. 18, lines 8-23), and a cosmetic or dermatological composition (col. 7, lines 45-48) comprising at least one water-soluble, poorly water- soluble, or water-insoluble cosmetic agent (col. 2, lines 2-6, line 40; col. 4, line 59) and a cosmetically or dermatologically acceptable carrier (col. 8, lines 24-27; col. 13, lines 46-59).

In Reference to Claim 5

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids, α- hydroxy acids, β-hydroxy acids, α-2 adrenergic inhibitors, β-adrenergic agonists, aromatase inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol, mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 3, line 55).

In Reference to Claim 8

The system according to claim 5 (see rejection of claim 5 above), wherein the cosmetic agent is hydroquinone (col. 4, lines 65-66).

In Reference to Claim 10

The system according to claim 1 (see rejection of claim 1 above), wherein the cosmetic or dermatological composition further comprising a pharmaceutical agent (col. 2, lines 9-11; col. 4, lines 49-50).

In Reference to Claim 11

The system according to claim 10 (see rejection of claim 10 above), wherein the pharmaceutical agent is an antibacterial agent (col. 2, lines 9-11; col. 4, lines 49-50).

In Reference to Claim 14

A method for treating a skin condition (col. 5, lines 24-32; col. 36, lines 62-64) in a subject comprising the steps of:

(i) generating at least one micro-channel (col. 18, lines 8-23) in a region of skin of a subject suffering from a skin condition (col. 28, lines 56-57); and

(ii) topically applying (col. 8, lines 17-18, lines 37-38) a dermatologically effective amount of a cosmetic or dermatological composition (col. 7, lines 45-48) comprising at least one water-soluble, poorly water-soluble, or water-insoluble cosmetic agent (col. 2, lines 2-6, line 40; col. 4, line 59) and a cosmetically or dermatologically acceptable

carrier (col. 8, lines 24-27; col. 13, lines 46-59) to the region of the skin in which at least one micro-channel is present (col. 8, lines 41-46) so as to improve the skin condition of said subject (col. 5, lines 24-32).

In Reference to Claim 15

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids, α-hydroxy acids, β-hydroxy acids, α-2 adrenergic inhibitors, β-adrenergic agonists, aromatase inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol, mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 3, line 55).

In Reference to Claim 18

The method according to claim 15 (see rejection of claim 15 above), wherein the cosmetic agent is hydroquinone (col. 4, lines 65-66).

In Reference to Claim 20

The method according to claim 14 (see rejection of claim 14 above), wherein the cosmetic or dermatological composition further comprising a pharmaceutical agent (col. 2, lines 9-11; col. 4, lines 49-50).

In Reference to Claim 21

The method according to claim 20 (see rejection of claim 20 above), wherein the pharmaceutical agent is an antibacterial agent (col. 2, lines 9-11; col. 4, lines 49-50).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference Avrahami (US Patent No. 6,148,232), which describes a system for producing microchannels within the stratum corneum to allow transdermal drug delivery. The reference Henley et.al. (Patent Application Publication No. 2003/0199808), which describes a system for delivering caffeine, salicylic acid, hydroquinone, or other active agents within the body via electrical energy.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4124